Film-Coating Tablets

The sugarcoating process, as described, not only is tedious, time-consuming, and specialized, requiring the expertise of highly skilled technicians, but also results in coated tablets that may be twice the size and weight of the original uncoated tablets. Also, sugarcoated tablets may vary slightly in size from batch to batch and within a batch. All of these factors are important considerations for a manufacturer. From a patient's point of view, large tablets are not as easily swallowed as are small tablets.

The film-coating process, which places a thin, skin-tight coating of a plastic-like material over the compressed tablet, was developed to produce coated tablets having essentially the same weight, shape, and size as the originally compressed tablet. Also, the coating is thin enough to reveal any identifying monograms embossed in the tablet during compression by the tablet punches. Film-coated tablets also are far more resistant to destruction by abrasion than are sugarcoated tablets. However, like sugarcoated tablets, the coating may be colored to make the tablets attractive and distinctive.

Film-coating solutions may be nonaqueous or aqueous. The nonaqueous solutions contain the following types of materials to provide the desired coating to the tablets:

1. A *film former* capable of producing smooth, thin films reproducible under conventional coating conditions and applicable to a variety of tablet shapes. Example: cellulose acetate phthalate
2. An *alloying substance* providing water solubility or permeability to the film to ensure penetration by body fluids and therapeutic availability of the drug. Example: polyethylene glycol
3. A *plasticizer* to produce flexibility and elasticity of the coating and thus provide durability. Example: castor oil
4. A *surfactant* to enhance spreadability of the film during application. Example: polyoxyethylene sorbitan derivatives
5. *Opaquants* and *colorants* to make the appearance of the coated tablets handsome and distinctive. Examples: opaquant, titanium dioxide; colorant, FD&C or D&C dyes
6. *Sweeteners*, *flavors*, and *aromas* to enhance the acceptability of the tablet by the patient. Examples: sweeteners, saccharin; flavors and aromas, vanillin
7. A *glossant* to provide luster to the tablets without a separate polishing operation. Example: beeswax
8. A *volatile solvent* to allow the spread of the other components over the tablets while allowing rapid evaporation to permit an effective yet speedy operation. Example: alcohol mixed with acetone

Tablets are film coated by application or spraying of the coating solution on the tablets in ordinary coating pans. The volatility of the solvent enables the film to adhere quickly to the surface of the tablets.

Because of both the expense of the volatile solvents used in the film-coating process and the environmental problem of the release of solvents, pharmaceutical manufacturers generally favor the use of aqueous solutions. One of the problems attendant to these, however, is slow evaporation of the water base compared to the volatile organic solvent–based solutions. One commercial water-based colloidal coating dispersion called Aquacoat (FMC Corporation) contains a 30% ethyl cellulose pseudolatex. Pseudolatex dispersions have a high solid content for greater coating ability and a relatively low viscosity. The low viscosity allows less water to be used in the coating dispersion, requiring less evaporation and reducing the likelihood that water will interfere with tablet formulation. In addition, the low viscosity permits greater coat penetration into the crevices of monogrammed or scored tablets. A plasticizer may be added to assist in the production of a dense, relatively impermeable film with high gloss and mechanical strength. Other aqueous film-coating products use cellulosic materials such as methylcellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose as the film-forming polymer.